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10 July 2009

Freehills Patent & Trade Mark Attorneys Level 43 101 Collins Street Melbourne VIC 3000 Australia

Your Ref: M81012613:SRC:ak

Examiner's first report on patent application no. 2004266324 by Amorfix Life Sciences Ltd

Last proposed amendment no. 1

Dear Madam/Sir,

Forecast and Control of the Control

Australia

Phone: 1300 651 010

I am replying to the request for examination. I have based this report on the pamphlet and the statement of proposed amendments under S104 of 25 September 2007. I have examined the application and I believe that there are lawful grounds of objection to the application. These grounds of objection are:

- 1. There is no Notice of Entitlement on file. You will need to file one because an application without a Notice of Entitlement cannot be accepted.
- 2. The specification does not comply with Section 40(4) because the claims do not relate to one invention only. The following inventions have been identified:
 - Claims 1 59 and 68 70 relate to methods and kits for detecting whether a candidate polypeptide is in a wild type or non-wild type conformation.
 - Claims 60, 62, 64 and 66 relate to a peptide having a sequence of DLGKGGNEESTKTGNAGS and antibodies specific for said peptide.
 - Claims 61, 63, 65 and 67 relate to a peptide having a sequence of NPLSRKHGGPKDEE and antibodies specific for said peptide.

The abovementioned groups do not share any common technical features that may represent a special technical feature. As such, it is appropriate to classify each group as a separate invention. This examination has been restricted to the first mentioned invention (ie. Claims 1-59 and 68-70) and comment on each of the further inventions is withheld.

Please note that no International Search has been conducted on the further inventions identified above. Should the applicant wish to pursue these inventions at a further report stage, additional time to that outlined in our customer service charter would be required to conduct a full search and examination. The approximate time for a full search and examination is 8 weeks.

3. Claims 50 - 58 are not for a manner of manufacture within the meaning of Sub-section 18(1) of the Patents Act. These claims merely define a kit or pack of known integers, and therefore do not define a "patentable combination".

Whilst there may be patentable subject matter when known integers are applied simultaneously or sequentially to produce a new product or interacting mixture, the claim has not defined how the kit or pack, by its construction, will in normal use ensure the simultaneous or sequential application of the integers.

It is noted that a kit or pack does not become a manner of manufacture within the meaning of subsection 18(1) merely by the incorporation into the claim of written information directed to the use of that kit or pack.

It is further noted however, that a kit "when used" in the methods of the invention may be viewed as satisfying the manner of manufacture requirements.

4. Pursuant to objection 3, claims 50 – 58 prima facie lack an inventive step, as the claims merely define a kit of known integers. The integers defined in said claims are known from the prior art – for example see Bolton, D.C. et al. Journal of Virology, 1991, 65(7): 3667 – 3675* in which the specific antibodies and chemical blocking agents defined in said claims are disclosed.

* cited in the ISR and IPRPI.

I apologise for any inconvenience resulting from your application not being considered within the time limit set out in our Customer Service Charter.

You have 21 months from the date of this report to overcome all my objection(s) otherwise your application will lapse.

You will need to pay a monthly fee for any response you file after 12 months from the date of the first report.

You will also need to pay any annual continuation fees that apply. These will normally be first due five years from the filing date. Please note however that earlier commencement dates apply for divisional applications.

Information about fees may be obtained by phoning 1300 651 010.

Yours faithfully,

JAMES ALDERMAN
Patent Examination B

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